Claim 5 - 35 U.S.C. § 103 (Ketcham in view of Maehara et al '234)

Claim 6 - 35 U.S.C. § 103 (Ketcham in view of Maehara et al '234, further in view of TSI Inc. Catalog).

Claims 4 to 6 have been amended herein and are believed to currently be in condition for allowance over the prior art of record.

In claim 4, the follow language has been added at the end of the claim following the bracketed deletion shown in the attached amended claim set:

> ...and wherein a volume of liquid is supplied to a chamber defined in part by said membrane, and wherein dispensing involves a reduction in the volume of liquid within the chamber during a dispensing operation prior to a step of replenishment of liquid to be dispensed.

Support for the above addition in claim 4 can be found, inter alia, in column 4, lines 50-52 (see also the paragraph bridging columns 4 and 5 providing example of one possible manner of replenishment).

The combination of method steps in claim 4 is respectfully submitted to patentably distinguish claim 4 over the above combination fo Ketcham in view of DE '552 (as well as the other references of record). The Ketcham reference relies on the forcing of a liquid stream under pressure from a liquid source (liquid feed tube 11) into a chamber 10 and contemporaneously through the orifice plate (see the Abstract for example). The pressurized liquid stream is then broken up by the vibrating plate. Accordingly, at the time of dispensing, there is a continued quantity of liquid supplied to the chamber partially defined by the orifice plate such that a reduction in initial liquid volume does not occur during a dispensing operation in the chamber. Nor would it have been obvious to modify the Ketcham reference with an

alternative method than the pressurized system which is described as being well suited for its intended function, and there is lacking any disclosure or suggestion in the prior art to alter the system described as being well suited for the disclosed purpose in Ketcham.

Claims 5 and 6 currently include the following language (added to the end of the claims)

> ...and wherein the flow rate is in the range of 10 to 20 cubic millimeters per second which flow rate and droplet size are suitable for delivery of an atomized product to a patient's lungs.

Accordingly, claims 5 and 6 currently describe a combination of method steps wherein a flow rate is provided that (as described in the supporting disclosure in the second full paragraph of column 7, and in conjunction with the other method steps in claims 5 and 6) allows for the generation of a fine mist that is sufficiently suspended (e.g., not driven under pressure) so as to render it suited for delivery of pharmaceutical product to the lungs of a patient (which is very difficult to do due to the need to supply a sufficiently dispersed floating, low velocity spray which will be accepted by the highly differentiating receptors in the lungs).

Claim 6 further includes an added correlation between particle size and the associated flow rate.

For the reasons outlined above, the pressurized dispensing system is not suited like the design of the present invention to achieve the required characteristics of a fine mist for lung reception. Nor would it have been obvious to entirely redesign the pressurized system of Ketcham to achieve the combined method required of the present invention for similar results as outlined above in the rejection of claim 4 discussion.

Accordingly, it is respectfully submitted that all claims currently stand in condition for

allowance and confirmation of the same at the Examiner's earliest convenience is respectfully requested. If for any reason, however, the present case is not deemed to be in immediate condition for allowance (e.g., a remaining informality), the Examiner is invited to telephone the undersigned. Also, if there are any non-covered fees associated with this filing, authorization is provided to charge such fees to Deposit Account No. 02-4300.

Respectfully submitted,

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AMENDMENT PURSUANT TO 37 CFR 1.173

4. (Twice Amended) A method [as claimed in claim 3] of dispensing a liquid as an atomised spray comprising the steps of

maintaining the liquid in contact with a rear surface of a perforate membrane defining an array of holes, each hole being flared such that the cross-section of each hole narrows in a direction from the rear surface towards a front surface of the membrane, said membrane being stiffened by means of a grid of support elements, and said membrane having a sheet defining the array of holes and having thickened portions constituting the support elements,

and vibrating said membrane with the grid of support elements and flared hole such that droplets of the liquid are dispensed through the holes as an atomised spray

[wherein wetting of the front surface of the membrane by the liquid is inhibited by means of a liquid repellant surface coating applied to the front surface]

and wherein a volume of liquid is supplied to a chamber defined in part by said membrane, and wherein dispensing involves a reduction in the volume of liquid within the chamber during a dispensing operation prior to a step of replenishment of liquid to be dispensed.

5. (Twice Amended) A method [as claimed in claim 3] of dispensing a liquid as an atomised spray comprising the steps of

maintaining the liquid in contact with a rear surface of a perforate membrane defining an array of holes, each hole being flared such that the cross-section of each hole narrows in a

direction from the rear surface towards a front surface of the membrane, said membrane being stiffened by means of a grid of support elements, and said membrane having a sheet defining the array of holes and having thickened portions constituting the support elements,

and vibrating said membrane with the grid of support elements and flared hole such that droplets of the liquid are dispensed through the holes as an atomised spray

wherein the liquid comprises a pharmaceutical product in aqueous solution or suspension,

and wherein the flow rate is in the range of 10 to 20 cubic millimeters per second which flow rate and droplet size are suitable for delivery of an atomized product to a patient's lungs.

6. (Twice Amended) A method [as claimed in claim 3] of dispensing a liquid as an atomised spray comprising the steps of

maintaining the liquid in contact with a rear surface of a perforate membrane defining an array of holes, each hole being flared such that the cross-section of each hole narrows in a direction from the rear surface towards a front surface of the membrane, said membrane being stiffened by means of a grid of support elements, and said membrane having a sheet defining the array of holes and having thickened portions constituting the support elements,

and vibrating said membrane with the grid of support elements and flared hole such that droplets of the liquid are dispensed through the holes as an atomised spray

wherein the liquid comprises a pharmaceutical product and the holes have a diameter at the front surface in the range 3 to 7 microns,

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and wherein the flow rate is in the range of 10 to 20 cubic millimeters per second which flow rate and droplet size are suitable for delivery of an atomized product to a patient's lungs.